DEPARTMENT OF HEALTH & HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

PHILADELPHIA DISTRICT

900 U.S. Customhouse
2nd and Chestnut Streets
Philadelphia, PA 19106

Telephone: 215-597-4390

D1154B

WARNING LETTER

February 3, 1997

97-PHI-13

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

GEN. SPEC.
RELEASE
F# _____ DATE _____
Reviewed by: Wm. W. Kuebler

David Carlin, Chief Executive Officer
M & Q Plastics Products
1364 Welsh Road Suite A-1
North Wales, PA 19454

During an inspection of your film extrusion plant located in Schuylkill Haven, PA which ended on January 13, 1997 our Investigator, Edward Mc Donald, determined that your firm manufactures nylon film which is a device as defined by Section 201(h) of the Federal Food, Drug and Cosmetic Act(the Act).

The above stated inspection revealed that this device is adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing storage, or installation are not in conformance with Good Manufacturing Practice(GMP) for Medical Devices Regulation, as specified in Title 21, Code of Federal Regulation(21 CFR), Part 820, as follows:

1. You have not conducted periodic quality assurance audits in accordance with your written procedures. These procedures call for semi-annual audits until compliance is achieved and then annual audits. You have performed no quality assurance audits in the calendar year 1996. [21 CFR 820.20(b)]

2. You have no written procedures for calibration of process control instruments, nor have you calibrated the instruments in use, or maintained logs of such calibrations. Undocumented equipment, among others, includes: [redacted] thermometer, [redacted] thickness gauge [redacted] burst test gauges, tensile tester load gauges, and temperature and pressure gauges used on the [redacted] sealing machine for sterilizer bags. [21 CFR 820.61]

3. You have released and distributed film products which failed to meet your finished product specifications. For example, [redacted] film specified at 1.6 mil +/-10% was released with measurements of

1.3 and 1.35 mils. Also, [redacted] film specified at 1.6 mil +/-15% was released at 2.2 mils. [21 CFR 820.100]

4. You have no written maintenance/cleaning procedures or schedules for the equipment used in the extrusion process, nor do you have them for the compressed air system used to blow the film. [21 CFR 820.60(a)]

We also note that you have no written procedure for adjusting the temperature of the #21 bag sealer. Also, you have no formal calibration log for the [redacted] blender.

We acknowledge receipt on January 21, 1997 of Mr. Harold A. Brenneman's response to the observations listed on the form FDA-483 presented to him at the close of the inspection. The responses appear adequate to correct the conditions observed. The letter will be placed in your firm's official file. The corrections will be verified at the next inspection.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the FDA-483 issued at the closeout of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems you must promptly initiate permanent corrective actions. Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no pending applications for premarket approval(PMA's) or export approval requests will be approved and no premarket notifications (Section 510(k)'s) will be found substantially equivalent for products manufactured at the facility in which the above GMP violations were found until the violations have been corrected. You should take prompt action to correct these deviations. Failure to correct these deviations promptly may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction and/or civil penalties.

Please verify to this office, in writing, within 15 working days of receipt of this letter, that the specific steps you have described in your response to the FDA-483 are being taken to correct the noted violations, and make corrections to any underlying systems problems necessary to assure that similar violations will not

recur. If corrective action cannot be completed within the time frames cited, state the reason for the delay and the time within which corrections will be completed.

Your reply should be directed to William W. Knipe, Compliance Officer at the address above.

Sincerely yours,

Diana Kolaitis
District Director

cc: Pennsylvania Department of Health
132 Kline Plaza Suite A
Harrisburg, PA 17104
Attention: Robert E. Bastian, Director
Division of Primary Care and Home Health Services